

**PART 123—RULES OF PRACTICE
GOVERNING PROCEEDINGS
UNDER THE VIRUS-SERUM-TOXIN
ACT**

§ 123.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A, title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the Virus-Serum-Toxin Act.

(Sec. 2, 32 Stat. 792, 37 Stat. 832–833 (21 U.S.C. 111, 151–158))

[42 FR 10960, Feb. 25, 1977]

**PART 124—PATENT TERM
RESTORATION**

Subpart A—General Provisions

Sec.

124.1 Scope.

124.2 Definitions.

Subpart B—Eligibility Assistance

124.10 APHIS liaison with PTO.

Subpart C—Regulatory Review Period

124.20 Patent term extension calculation.

124.21 Regulatory review period determination.

124.22 Revision of regulatory review period determination.

124.23 Final action on regulatory review period determination.

Subpart D—Due Diligence Petitions

124.30 Filing, format, and content of petitions.

124.31 Applicant response to petition.

124.32 APHIS action on petition.

124.33 Standard of due diligence.

Subpart E—Due Diligence Hearing

124.40 Request for hearing.

124.41 Notice of hearing.

124.42 Hearing procedure.

124.43 Administrative decision.

AUTHORITY: 35 U.S.C. 156; 7 CFR 2.22, 2.80, and 371.2(m).

SOURCE: 58 FR 11369, Feb. 25, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 124.1 Scope.

(a) This part sets forth procedures and requirements for APHIS review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156—Extension of patent term. Responsibilities of APHIS include:

(1) Assisting PTO in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to APHIS's regulatory review period determinations; and

(4) Conducting hearings to review initial APHIS findings on due diligence challenges.

(b) The regulations in this part are designed to be used in conjunction with regulations issued by PTO concerning patent term extension which may be found at 37 CFR 1.710 through 1.785.

§ 124.2 Definitions.

Animal and Plant Health Inspection Service (APHIS). The agency in the Department of Agriculture responsible for licensing veterinary biological products under the Virus-Serum-Toxin Act.

Applicant. Any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking extension of the term of a patent.

Due diligence petition. A petition submitted under § 124.30 of this part.

Informal hearing. A hearing which is not subject to the provisions of 5 U.S.C. 554, 556, and 557 and which is conducted as provided in 21 U.S.C. 321(y).

License applicant. Any person who, in accordance with part 102 of this chapter, submits an application to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture for a U.S. Veterinary Biological Product License.

Patent. A patent issued by the Patent and Trademark Office of the United States Department of Commerce.

Person. Any individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing.